

8/601,005

PCT/SE95/01542

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Washington D.C. 20231
United States of America

in its capacity as elected Office

Date of mailing (day/month/year)

08 July 1996 (08.07.96)

International application No.

PCT/SE95/01542

Applicant's or agent's file reference

D 1371-1 WO

International filing date (day/month/year)

19 December 1995 (19.12.95)

Priority date (day/month/year)

22 December 1994 (22.12.94)

Applicant

BÄCKSTRÖM, Kjell et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

17 June 1996 (17.06.96)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

J. Leitao

Telephone No.: (41-22) 730.91.11

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum)

D 1371-1 WO

Box No. I TITLE OF INVENTION
AEROSOL DRUG FORMULATIONS

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Astra Aktiebolag

S-151 85 Södertälje
Sweden

☐ This person is also inventor.

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Facsimile No.

+46 8 553 8 288 20

Teleprinter No.

19237 ASTRA S

State (i.e. country) of nationality:
SE

State (i.e. country) of residence:
SE

This person is applicant
for the purposes of:

☐ all designated
States

☒ all designated States except
the United States of America

☐ the United States
of America only

☐ the States indicated in
the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

BÄCKSTRÖM, Kjell
Notariegränden 4
S-226 47 Lund
Sweden

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only (If this check-box
is marked, do not fill in below.)

State (i.e. country) of nationality:
SE

State (i.e. country) of residence:
SE

This person is applicant
for the purposes of:

☐ all designated
States

☐ all designated States except
the United States of America

☒ the United States
of America only

☐ the States indicated in
the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf
of the applicant(s) before the competent International Authorities as:

☒ agent

☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Patent Department
Astra Aktiebolag
S-151 85 Södertälje
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Teleprinter No.

19237 ASTRA S

☐ Mark this check-box where no agent or common representative has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

DAHLBÄCK, Magnus
Sköldgränden 10
S-224 75 Lund
Sweden

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

SE

State (i.e. country) of residence:

SE

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

JOHANSSON, Ann
Arkeologvägen 65
S-226 54 Lund
Sweden

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

SE

State (i.e. country) of residence:

SE

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

KÄLLSTRAND, Göran
Dragonvägen 1
S-237 32 Bjärred
Sweden

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

SE

State (i.e. country) of residence:

SE

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

LINDQVIST, Elisabet
Lärkvägen 4
S-227 31 Lund
Sweden

This person is:

- ☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

SE

State (i.e. country) of residence:

SE

This person is applicant for the purposes of:

☐ all designated States☐ all designated States except the United States of America☒ the United States of America only☐ the States indicated in the Supplemental Box☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (*mark the applicable check-boxes; at least one must be marked*):

Regional Patent

- ☒ **AP** ARIPO Patent: KE Kenya, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EP** European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (*if other kind of protection or treatment desired, specify on dotted line*)

National Patent (*if other kind of protection or treatment desired, specify on dotted line*):

- | | |
|---|--|
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> AT Austria | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> IS Iceland | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> KR Republic of Korea | |
| <input checked="" type="checkbox"/> KZ Kazakhstan | |
| <input checked="" type="checkbox"/> LK Sri Lanka | |
| <input checked="" type="checkbox"/> LR Liberia | |
| <input checked="" type="checkbox"/> LT Lithuania | |
| <input checked="" type="checkbox"/> LU Luxembourg | |
| <input checked="" type="checkbox"/> LV Latvia | |

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☒ **AL** Albania
- ☒ **LS** Lesotho
- ☒ **MK** Macedonia
- ☐

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (*Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.*)

Box N . VI PRIORITY CLAIMFurther priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1) SE	22 December 1994 (22.12.1994)	9404469-0	
item (2) SE	06 July 1995 (06.07.1995)	9502452-7	
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☐ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s) : _____
Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used): ISA / SE

Earlier search Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request.

Country (or regional Office):

SE

Date (day/month/year):

22 December 1994

Number:

SE 95/00053

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request : 4 sheets
 2. description : 8 sheets
 3. claims : 5 sheets
 4. abstract : 1 sheets
 5. drawings : _____ sheets

Total : 18 sheets

This international application is accompanied by the item(s) marked below:

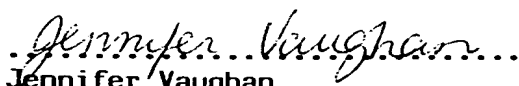
1. ☒ separate signed power of attorney
 2. ☒ copy of general power of attorney
 3. ☐ statement explaining lack of signature
 4. ☒ priority document(s) identified in Box No. VI as item(s):
 5. ☒ fee calculation sheet
 6. ☐ separate indications concerning deposited microorganisms
 7. ☐ nucleotide and/or amino acid sequence listing (diskette)
 8. ☒ other (specify): ITS SE95/00053

Figure No. _____ of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Södertälje, December 19, 1995


Jennifer Vaughan
Patent Department, Astra Aktiebolag

For receiving Office use only

1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority specified by the applicant: ISA /	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference D 1371-1 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE95/01542	International filing date (day/month/year) 19.12.1995	Priority date (day/month/year) 22.12.1994
International Patent Classification (IPC) or national classification and IPC ₆ A61K 9/12, A61K 47/12, A61K 47/24, A61K 47/26, A61K 47/28		
Applicant Astra Aktiebolag et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 17.06.1996	Date of completion of this report 03.04.1997
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Telex 17978 PATOREG-S	Authorized officer Anneli Jönsson Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE95/01542

I. Basis of the report

1. This report has been drawn on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

- ☐ the international application as originally filed.
- ☒ the description, pages 1-8, as originally filed,
 pages _____, filed with the demand,
 pages _____, filed with the letter of _____,
 pages _____, filed with the letter of _____.
- ☒ the claims, Nos. _____, as originally filed,
 Nos. _____, as amended under Article 19,
 Nos. _____, filed with the demand,
 Nos. 1-33, filed with the letter of 11.03.1997,
 Nos. _____, filed with the letter of _____.
- ☐ the drawings, sheets/fig _____, as originally filed,
 sheets/fig _____, filed with the demand
 sheets/fig _____, filed with the letter of _____,
 sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE95/01542

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 32

because:

☒ the said international application, or the said claims Nos. 32
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Se PCT Rule 67.1(iv)

Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE95/01542

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-31</u>	YES
	Claims	<u>33</u>	NO
Inventive step (IS)	Claims	<u>1-31</u>	YES
	Claims	<u>33</u>	NO
Industrial applicability (IA)	Claims	<u>1-31, 33</u>	YES
	Claims		NO

2. Citations and explanations

The claimed invention relates to a pharmaceutical aerosol formulation. The composition comprises a HFA propellant, a medicament and a surfactant. The specific classes of surfactants intended are those that are suitable together with the HFA propellant, for example, C₈-C₁₆ fatty acid or salt thereof, a bile salt, a phospholipid or an alkyl saccharide. A method for the manufacture of the pharmaceutical aerosol formulation and the use of said formulation are also claimed.

The claims have been amended by the letter filed on 11 March, 1997. Claim 1 has been amended by restrictions of the phospholipid to compounds claimed in original claims 8, 9, 10 and 11. Claim 33 is new, claiming a pharmaceutical aerosol formulation comprising a HFA propellant; a medicament, selected from formoterol fumarate, budesonide and ipratropium bromide, and a surfactant.

Document WO 9111495 A1 discloses a pharmaceutical aerosol-composition containing a drug suitable for inhalation, a propellant and a surfactant. The propellant is a mixture of, for example, hydrofluorocarbons such as P134a, P227 and P152 a, i.e. the same propellants intended for use in the presently claimed invention. The surfactant can be a phospholipid. The phospholipid used is soya lecithin and not one of the phospholipids used in the claimed invention. The examples 3 and 8 in this document both disclose compositions comprising ipratropium bromide, HFA propellant and a phospholipid. Therefore, claim 33 lacks novelty. The document only discloses the general state of the prior art of the subject matter of claims 1-31. However, the invention according to claims 1-31 is considered to involve novelty, inventive step and industrial applicability.

.../...

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE95/01542

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V.

Document EP 518 600 A1 discloses an aerosol formulation comprising 1,1,1,2,3,3,3 heptafluoropropane (i.e. P 227), a medicament, optionally an excipient and optionally a surfactant (see page 3, line 24-58). The surfactants preferred are oleic acid (a C₁₈-acid) or soya lecithin (a phospholipid). The oleic acid is not included in the range of fatty acids claimed in claim 1 and other phospholipids than soya lecithin are not suggested. The document does not disclose the surfactants used in the composition according to claims 1-32. Suggestions of compositions containing ipratropium bromide as medicament are made (page 5, line 42), but no example with that medicament is shown. Therefore, the document is of less relevance than WO9111495 and only discloses the general state of the prior art.

Accordingly, the claimed invention according to claims 1-31 is considered to fulfil the requirements for novelty, inventive step and industrial applicability. Claim 33 lacks novelty.